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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,867	11/20/1998	BRIAN KELSALL	14014.0312	9637

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	28

DATE MAILED: 03/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/196,867	Kelsall et al
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Feb 12, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
   (b) ☐ they raise the issue of new matter. (See NOTE below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____
4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   See attached
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
   Claim(s) allowed: _____
   Claim(s) objected to: _____
   Claim(s) rejected: *1-8 and 10*
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .
11. ☐ Other:

DETAILED ACTION

1. Applicant's after-amendment, filed 2-12-02 (Paper No. 27), is acknowledged. Claims 1-8 and 10 are pending and presently under consideration.

2. The rejections of record can be found in the previous Office Action mailed 10-23-01 (Paper No. 26), and are maintained essentially for the reasons of record.

It is also noted that no supplemental IDS has yet been received by the office, though applicant indicated in an amendment filed 8-14-01 that a supplemental IDS would be submitted along with the executed declaration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, In such full, clear, concise, and exact terms as to enable any person skilled In the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. MAINTAINED Claims 1-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-8 and 10 are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "wherein the ligand is not an antibody having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.**

Applicant's amendment filed 8-14-01 (page 7) states "applicants explicitly recite monoclonal antibody 5C6 in the specification as a specific example of a member of the subgenus carved out of the claims by this limitation", said limitation being "wherein the ligand is not an antibody having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6". Further, Applicant's amendment filed 8-14-01 (page 7) states that the disclosure of references 8, 11, and 13 are incorporated by reference in their entireties as stated on page 25, lines 24-27 of the specification to describe the subgenus of antibodies having the myelomonocytic recruitment inhibitory activity of 5C6. However, Applicant's amendment filed 8-14-01 (page 6) points to support for said limitation to page 22, lines 27-28, of the instant specification where it is disclosed that prior to LPS injection, "Balb/C mice were given intraperitoneal injections of either CR3

antibodies (1 mg of clone M1/70 or 0.5 mg of 5C6, both of which are non-opsonizing antibodies (8, 32)." In applicant's after-final amendment filed 2-12-2002, applicants point out that referencing page 22 of the instant specification was to show the examiner that the recitation of monoclonal antibody 5C6 is supported at that place in the instant specification by a specific reference (i.e. reference 8). The specification further discloses in the same paragraph continuing on to page 23 that pretreatment of LPS-injected mice with M1/70 or 5C6 reduced the serum levels of IL-12. It is noted by the examiner that the instant specification as such does not disclose any specific characteristics distinguishing the two antibodies M1/70 and 5C6, and consequently does not disclose the concept that the antibodies M1/70 and 5C6 are each representative of two distinct genuses.

Applicant's position in their after-final amendment filed 2-12-02 on page 14, is that even without relying on subject matter from an incorporated document, it is clear from the instant specification that monoclonal antibody 5C6 is an antibody of the invention, with which the examiner agrees. The examiner also agrees with Applicant that the myelomonocytic recruitment inhibitory activity of 5C6 is an art recognized characteristic of this antibody as set forth in references 8 and 11, both of which are publicly available. However the examiner disagrees with applicant's further contention that it would be readily recognized by one of skill in the art on the basis of applicant's disclosure, that antibody 5C6 and other antibodies having these particular characteristics of 5C6 are included as a sub-genus within the applicant's invention. It is the examiner's position as stated above that there is no basis disclosed in the instant specification for the concept of carving a subgenus of monoclonal antibodies to complement receptor 3 based solely on the characteristic of having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6.

The examiner's position stated in the final office action mailed 10-23-01, that to incorporate material by reference, the host document / application must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973). In applicant's after-final amendment filed 2-12-02, on page 6, The applicant traverses the rejection on the grounds that the court in Advanced Display Systems never addresses the issue of whether the above described incorporation by reference was proper, and that furthermore it is applicant's belief that this summary has been taken out of context by the court. Applicant further provides a detailed examination of the facts in In re de Seversky to demonstrate how this case should have been interpreted. However, the examiner's position is that of the court, and as such requires that the host document / application must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents, and thus maintains that the incorporation by reference is not proper.

The examiner's position stated in the final office action mailed 10-23-01, Applicant has thus improperly inserted new matter by way of a negative limitation, In re Graselli, 218 USPQ 769. In applicant's amendment filed 2-12-02, on page 14, The applicant traverses the rejection on the grounds that there is precedent in the case law for an inventor to carve out, by negative limitation, less than the whole of what is described as his invention. However, for the reasons described above, it is not clear that applicants have disclosed or described their invention as particularly including a subgenus of the genus of monoclonal antibodies to complement receptor 3, wherein said subgenus is based solely on the characteristic of having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6.

In Purdue Pharma L.P. v Faulding Inc., 56 USPG2d 1481, 1486 (CA FC 2000) the Court noted with respect to In re Ruschig 379 F.2d 990, 154 USPQ 118 (CCPA 1967) that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say 'here is my invention.' In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See [In re Ruschig] at 994-95, 154 USPQ at 122; Fujikawa, 93 F.3d at 1570-71, 39 USPQ2d at 1905; Martin v. Mayer, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337(Fed. Cir. 1987) ("It is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure. ... Rather, it is a question whether the application necessarily discloses that particular device.'") (quoting Jepson v. Coleman, 314 F.2d 533, 536, 136 USPQ 647, 649-50(CCPA 1963))".

Furthermore the examiner notes that the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication requires that Applicant amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Therefore, though applicants arguments have been carefully considered, they are not deemed persuasive, and the rejection is maintained, essentially for the reasons of record.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-

5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640, Technology Center 1600
March 5, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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